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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,339	03/12/2002	Peter Jungblut	028622-0108	1997

7590 03/07/2006

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,339

Applicant(s)

JUNGBLUT ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44,45,48-57 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44,45,48-57,63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 January 2006 has been entered.

Claims 27-43 and 58-62 have been canceled. Claims 44, 48, 50, 51-57, 63, 64, 66, and 67 have been amended.

2. Claims 44, 45, 48-57, and 63-68 are pending and under consideration.

Rejections Withdrawn/Moot

3. The rejection of claims 58-62 under 35 U.S.C. 112, first paragraph, scope of enablement for identification of proteins by comparison of any/all other virulent strains of *Mycobacterium* to any/all other avirulent strains of *Mycobacterium* is moot in light of the cancelation of the claims.

4. The rejection of claims 58 and 62 under 35 U.S.C. 112, second paragraph, as being indefinite is moot in light of the cancelation of the claims.

5. The rejection of claims 48-50, 54-57, 64, 65, 67, and 68 under 35 U.S.C. 112, second paragraph, indefiniteness for being drawn to nonelected inventions, is withdrawn in light of the claim amendments.

6. The rejection of claim 51 under 35 U.S.C. 112, second paragraph, indefinite for depending from a nonelected claim 27, is withdrawn in light of the amendment of the claim.

7. The rejection of claims 44, 45, 48-57, and 63-68 under 35 U.S.C. 112, first paragraph, scope of enablement for identification of proteins by comparison of any/all other virulent strains

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of *Mycobacterium* to any/all other avirulent strains of *Mycobacterium* is withdrawn in light of the amendments of the claims.

8. The rejection of claims 44, 45 and 48-57 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendments of the claims.

9. The rejection of claims 49, 51, 52, 54, 65, and 68 under 35 U.S.C. 112, first paragraph, scope of enablement for vaccines, is withdrawn in light of the amendments of the claims.

Claim 57 depends from claim 56, but does not clarify the indefiniteness.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 44, 45, 48-50, and 63-68 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

An embodiment of the claims is a nucleic acid molecule coding for oxidoreductase (Rv0068) or hypothetical protein (Rv3407) from *M. tuberculosis*.

There is no recitation of isolation or purification. Therefore, the claims read on naturally occurring DNA in *M. tuberculosis*.

Claims 48, 50, 64, and 67 do not require a suitable means for detection or a pharmaceutically acceptable carrier because these are "options".

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 55 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how *M. tuberculosis* induces some of the listed diseases, e.g., leprosy.

14. Claims 56 and 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 56, it is unclear how one detects the presence of *M. tuberculosis* in a sample comprising contacting a nucleic acid composition with either pathogenic fragments or derivatives of whole *M. tuberculosis* other than nucleic acid.

15. Claims 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

Conclusion

16. No claims are allowed.

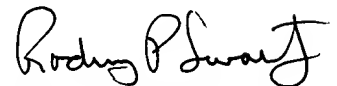
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

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March 2, 2006